

FDA ITACS Public Statuses

One of the features of FDA's Import Trade Auxiliary Communications System (ITACS) is the availability of what FDA has designated as statuses that can be displayed to the public. The following are statuses corresponding with many of the FDA admissibility decisions and activities used to record interim field and compliance actions which are recorded in FDA's Import system. They are meant to augment the 15 electronic statuses which are currently transmitted via the FDA/Customs Interface, as well as the larger set currently included in Notices of FDA Action. Some of the status text displayed as Public Statuses in ITACS have been modified to be more easily understood.

Audit Sample Received by FDA Lab
Compliance Response to Trade Communication - Please Refer to Notice of FDA Action
Detained - Refer to Notice of FDA Action for Violation Charges
Detained Without Physical Exam - Refer to Notice of FDA Action for Violation Charges
Detention Withdrawn - Pending Further FDA Compliance Review
Document Accepted
Document Failed Virus Scan
Document Rejected - Attempt to Resubmit
Document Submitted
Document Upload Failed
Documents Required
Entry Deficient - Please Refer to Notice of FDA Action for Details
Entry Documents Required - Notify FDA of Location for FDA Examination
Extension Granted - Refer to Notice of FDA Action for Response Deadline
Extension Request Denied
Extension Request Received
FDA Audit Lab Analysis Completed. FDA Compliance Staff are reviewing the line to determine admissibility. This status will be updated when that determination is made, and the final admissibility decision for this line

will be reflected in the Notice of FDA Action generated after that decision is recorded by FDA.
FDA Audit Lab Analysis in Process
FDA Audit Sample Collected
FDA Examination Completed
FDA Examination Pending
FDA Lab Analysis Completed. FDA Compliance Staff are reviewing the line to determine admissibility. This status will be updated when that determination is made, and the final admissibility decision for this line will be reflected in the Notice of FDA Action generated after that decision is recorded by FDA.
FDA Lab Analysis in Process
FDA Reconditioning Lab Analysis Completed. FDA Compliance Staff are reviewing the line to determine admissibility. This status will be updated when that determination is made, and the final admissibility decision for this line will be reflected in the Notice of FDA Action generated after that decision is recorded by FDA.
FDA Reconditioning Lab Analysis in Process
FDA Reconditioning Sample Collected
FDA Sample Collected
Field Exam Completed
Further Reconditioning Approved
Goods Were Not Available for FDA Examination - Notify FDA When Available
Hold All Lines - Do Not Devan
Hold All Lines - Do Not Devan - Documents Required
Hold All Lines - Do Not Devan - Documents Required - Notify FDA of Availability for Examination
Hold All Lines - Do Not Devan - Notify FDA of Availability for Examination
Hold All Lines - Documents Required
Hold All Lines - Documents Required - Notify FDA of Availability for Examination
Hold All Lines - Notify FDA of Location for FDA Examination

Hold Designated Lines - Notify FDA of Location for FDA Examination
Hold Pending Further Written Notice from FDA
Interface Error Contact FDA
Line Availability Received, FDA Examination Pending
Line Split Due Multiple Products Identified - See FDA Notice of Action for Details
May Proceed Rescinded - Hold for Further Information from FDA
May Proceed Without FDA Examination
Non FDA Lab Rejected - Additional Private Lab Submission Not Allowed
Non-FDA Analysis Rejected following Audit Sample - No Resubmission Allowed
Non-FDA Analysis Rejected following Audit Sample - Resubmission Allowed
Non-FDA Lab Rejected
Non-FDA Lab Rejected - Resubmission Allowed
Non-FDA Lab Report Received
Non-FDA Lab Under Review
Notify FDA of Location for FDA Examination
Partial Refusal - Inform FDA After Export or Destruction of Refused Portion
Partial Refusal - Inform FDA Before Export or Destruction of Refused Portion
Pending Review By FDA Compliance Staff
Private Laboratory Analysis Confirms Product is Violative
Proof of Export or Destruction Received
Reconditioned Materials Released
Reconditioning Completion Notification Received by FDA
Reconditioning Request (FDA-766) Denied
Reconditioning Request (FDA-766) Under Review
Reconditioning Request Approved - FDA Supervision Not Required

Reconditioning Request Approved - Contact FDA to Arrange Supervision
Reconditioning Request Conditionally Approved
Reconditioning Request Conditionally Approved - Contact FDA to Arrange Supervision
Reconditioning Request Conditionally Approved - Refer to Notice of FDA Action for Conditions
Reconditioning Request Denied - Resubmission Allowed
Reconditioning Request Incomplete - Resubmission Allowed
Reconditioning Supervision Waived - Contact FDA when Reconditioning is Complete
Reconditioning Unsatisfactory
Reconditioning Unsuccessful - Resubmission Allowed
Refusal Follow-up Completed
Refusal Rescinded - Product Still Detained
Refused - No Further FDA Action
Refused Inform FDA After Export
Refused Inform FDA After Export or Destruction
Refused Inform FDA Before Export
Refused Inform FDA Before Export or Destruction
Release Rescinded - Hold for Further Information from FDA
Released
Released With Comment - Future Violative Shipments May Be Detained
Sample Received by FDA Lab
Submission Under Technical Review
Submit Entry Documents to FDA (Invoice, B/L, CBP Entry Document)
Submit Proof of Export or Destruction to FDA (CBP Form and On-Board shipping records)